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09/744,350	05/22/2001	Francis X. Ignatious	00537-181002	5160

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EXAMINER

BORIN, MICHAEL L

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 07/30/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/744,350**

Applicant(s)  
**Ignatious**

Examiner  
**Michael Borin**

Art Unit  
**1631**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on May 15, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 17-48 is/are pending in the application.
- 4a) Of the above, claim(s) 23-27 and 30-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-22, 28, and 29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6,13 6) ☐ Other:

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## **DETAILED ACTION**

### ***Status of Claims***

1. Response to restriction requirement filed 05/15/03 is acknowledged. Applicant changed the elected group to claims 17-29. The election is made without traverse. Cancellation of claims drawn to non-elected groups is requested.

2. Further, in regard to election of species, applicant elected somatostatin analogue as a peptide, polylactide-co-glycolide containing COOH groups as a charged polyester, dichloromethane as an organic solvent, and sodium oleate as surfactant. It should be noted that there are no claims reading on the combination of species as claimed, because claims 28,29 reciting the elected peptide and polyester species depend on claim 23 which limits surfactant to polyvinyl alcohol. However, to expedite prosecution, and in anticipation of amendment of claims 23,24 to include the elected surfactant (sodium oleate), Examiner proceeded with the examination of the elected combination of species (assuming that claims 25-29 depend on claim 22 rather than on claim 24). Claims 23,24,26,27 are withdrawn from consideration as drawn to non-elected species.

Claims 17-22, 28, 29 are examined on merits to the extent they read on the elected species.

### ***Abstract***

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3. The abstract of the invention is not descriptive. The abstract does not reflect the elected invention. A new abstract is required which is clearly indicative of the invention to which the elected claims are directed.

***Sequence Listing***

4. The Sequence Listing has been transferred from the parent application.

***Claim Objections***

5. Claims 20,29 are objected for using the term "polymer" instead of more narrow term "polyester" used in the base claim 17.

***Claim Rejections - 35 USC § 103.***

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103<sup>o</sup> and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 17-22, 28, 29 are rejected under 35 U.S.C. 103(a) as obvious over Thompson et al. (US 5635216) in view of Fong et al (US 4383975)

The instant claims are drawn to oil-in-water method of preparing peptide-containing microcapsules comprising

- complexing a peptide with a charged polyester in an organic solvent to form a solution;
- dispersing the above solution in an aqueous solution containing surfactant;
- evaporating the organic solvent.

The elected species are: somatostatin analogue as a peptide, polylactide-co-glycolide containing COOH groups as a charged polyester, dichloromethane as an organic solvent, and sodium oleate as surfactant.

Thompson teaches method of preparing polyester microparticles containing peptides (e.g., somatostatin or its analogues) by mixing polylactide/polyglycolide with a peptide in an organic solution, such as dichloromethane, making an oil-in-water emulsion by dispersing the solution in an aqueous phosphate buffered solution

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containing a stabilizer, with subsequent evaporation of the organic solvent and recovering of microparticles. The amount of polyester in diclormethane is 3.6%. See col. 5 and example 1.

The polylactide/polyglycolide polyester used in the method contains certain amount of carboxylic acid moieties by virtue of its structure, so even though the reference does not describe it as "anionically functionalized", it reads on the elected polyester species.

In regard to surfactant used, the reference does teach presence of other surfactants recited in the instant claims (e.g., polyvinyl alcohol), but does not specifically teach the elected species, sodium oleate. Selection of such surfactant, however, would have been quite obvious to one skilled in the art at the time the invention was made because Fong et al (US 4384975) demonstrates that sodium oleate as an advantageous surfactant in preparing microparticles using oil-in-water process because it allows successful separation of microparticles due to stabilizing emulsion against uncontrolled agglomeration and coalescence during solvent removal. See col. 3, lines 10-14, col. 4, claim 9.

6. Claims 17-22, 28, 29 are rejected under 35 U.S.C. 103(a) as obvious over Orsolini (US 5445832) in view of Shalaby (US 5672659), and further in view of Fong et al (US 4383975).

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The instant claims are drawn to oil-in-water method of preparing peptide-containing microcapsules comprising

- complexing a peptide with a charged polyester in an organic solvent to form a solution;
- dispersing the above solution in an aqueous solution containing surfactant;
- evaporating the organic solvent.

The elected species are: somatostatin analogue as a peptide, polylactide-co-glycolide containing COOH groups as a charged polyester, dichloromethane as an organic solvent, and sodium oleate as surfactant.

Orsolini (US 5445832) teaches method of preparing microcapsules for sustained and controlled release of peptides (such as somatostatins and analogues thereof) whereby peptide is converted into a water-insoluble salt which is suspended in an organic solvent (such as dichloromethane) together with a polyester, such as polylactide/polyglycolide, and suspension is dispersed in an aqueous medium comprising an appropriate surfactant. See col. 3, and claims 1-6.

The reference teaches that the objective of the first method step is to convert peptide into water-insoluble state. The referenced method differs from the corresponding step of the claimed method in that it achieves a water-insoluble derivative of a peptide by converting it into a salt (e.g., stearate, palmitate, etc.) before adding the salt to

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solution of polyester in an organic solution, whereas the instant method converts peptide into a water-insoluble complex with a polyester in the organic solution. However, the method of obtaining water-insoluble complexes of a peptides with a anionically functionalized polyester is known in the art. Thus, Shalaby (US 5672659) teaches method of preparing microcapsules containing peptides (such as somatostatins and analogues thereof) whereby a polyester containing one or more free COOH groups (i.e., anionically functionalized polyester using language of instant claims) is combined with a peptide. See cols. 1-2, and claims 10, 12, 29. Shalaby teaches that the advantage of such ionic molecular conjugates in sustained release peptide compositions is capability of control of releasing peptide from the conjugate in vivo (see col. 2, lines 40-46). Therefore, one skilled in the art at the time the invention was made would be motivated to use peptide conjugates of Shalaby instead of peptide salts of Orsolini in preparing microcapsules for sustained and controlled release of peptides.

In regard to surfactant used, although Orsolini does not teach sodium oleate as surfactant, the reference does teach that aqueous media should contain an appropriate surfactant (col. 3, line 45). One would be motivated to use sodium oleate as a surfactant, because Fong et al (US 4384975) demonstrates that sodium oleate is an advantageous surfactant in preparing microparticles using oil-in-water process because it allows successful separation of microparticles due to stabilizing



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emulsion against uncontrolled agglomeration and coalescence during solvent removal.

See col. 3, lines 10-14, col. 4, claim 9.

***Conclusion.***

No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

July 24, 2003

mlb

MICHAEL BORIN, PH.D  
PRIMARY EXAMINER

